IUCLID

Data Set

Existing Chemical	:	ID: 96-49-1
CAS No.	:	96-49-1
EINECS Name	:	ethylene carbonate
EC No.	:	202-510-0
Molecular Formula	:	C3H4O3

Producer related part

Company	:	ToxWorks
Creation date	:	05.06.2002

Substance related part

Company	:	ToxWorks
Creation date	:	05.06.2002
Status	:	
Memo	:	
Printing date	:	09.02.2004
Revision date	:	
Date of last update	:	09.02.2004
Number of pages	:	27
Chapter (profile)	:	Chapter: 1, 2, 3, 4, 5, 6, 7, 8, 10
Reliability (profile)	:	Reliability: without reliability, 1, 2, 3, 4
Flags (profile)	:	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1.0.1 APPLICANT AND COMPANY INFORMATION

Type	:	cooperating company
Name	:	ToxWorks, Bridgeton, New Jersey
Contact person	:	Dr. George Cruzan
Date	:	06.06.2002
Street	:	1153 Roadstown Road
Town	:	08302 Bridgeton, New Jersey
Country	:	United States
Phone	:	856-453-3478
Telefax	:	856-453-3479
Telex	:	
Cedex	:	
Email	:	ToxWorks@aol.com
Homepage	:	

09.09.2002

05.06.2002

1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

1.0.3 IDENTITY OF RECIPIENTS

1.0.4 DETAILS ON CATEGORY/TEMPLATE

1.1.0 SUBSTANCE IDENTIFICATION

IUPAC Name	:	1,3-dioxolan-2-one
Smiles Code	:	
Molecular formula	:	
Molecular weight	:	
Petrol class	:	

05.06.2002

1.1.1 GENERAL SUBSTANCE INFORMATION

Purity type	:	typical for marketed substance
Substance type	:	organic
Physical status	:	solid
Purity	:	
Colour	:	practically colorless
Odour	:	odorless

05.06.2002

1.1.2 SPECTRA

1.2 SYNONYMS AND TRADENAMES

ethylene carbonate

05.06.2002

ethylene glycol carbonate

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1.3 IMPURITIES

Purity	:	typical for marketed substance
CAS-No	:	75-21-8
EC-No	:	200-849-9
EINECS-Name	:	ethylene oxide
Molecular formula	:	C2H4O
Value	:	ca. .025 % w/w
Source	:	Texaco Material Safety Data Sheet, 1988

05.06.2002

1.4 ADDITIVES

1.5 TOTAL QUANTITY

1.6.1 LABELLING

1.6.2 CLASSIFICATION

1.6.3 PACKAGING

1.7 USE PATTERN

1.7.1 DETAILED USE PATTERN

1.7.2 METHODS OF MANUFACTURE

Origin of substance	:	Synthesis
Type	:	Production
Remark	:	Produced by the addition of carbon dioxide to ethylene oxide in presence of ammonium, alkali metal salt, or Et4NBr as catalyst.

Source : NLM online, HSDB, 6/5/02 .
29.10.2002

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1.8 REGULATORY MEASURES

1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.8.2 ACCEPTABLE RESIDUES LEVELS

1.8.3 WATER POLLUTION

1.8.4 MAJOR ACCIDENT HAZARDS

1.8.5 AIR POLLUTION

1.8.6 LISTINGS E.G. CHEMICAL INVENTORIES

1.9.1 DEGRADATION/TRANSFORMATION PRODUCTS

1.9.2 COMPONENTS

1.10 SOURCE OF EXPOSURE

1.11 ADDITIONAL REMARKS

1.12 LAST LITERATURE SEARCH

1.13 REVIEWS

2.1 MELTING POINT

Value	:	= 36.4 °C
Sublimation	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	Calculated value by MPBPWIN v1.40 = 12.9 deg C Handbook data
Reliability	:	(2) valid with restrictions original data not reviewed
Flag	:	Critical study for SIDS endpoint

06.09.2002 (19)

2.2 BOILING POINT

Value	:	= 248 °C at
Decomposition	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	
Remark	:	Calculated value by MPBPWIN v1.40 = 287 Handbook data
Reliability	:	(2) valid with restrictions original data not reviewed
Flag	:	Critical study for SIDS endpoint

06.09.2002 (19)

2.3 DENSITY

Type	:	relative density
Value	:	= 1.3214 at 39 °C
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	
Remark	:	Handbook data
Reliability	:	(2) valid with restrictions original data not reviewed
Flag	:	Critical study for SIDS endpoint

06.09.2002 (19)

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

Value	:	= 1.307 hPa at °C

Remark	:	estimated value by MPBPWIN v1.40 = 0.0218 mm Hg at 25 deg C, 2.906 hPa. low vapor pressure
Reliability	:	(2) valid with restrictions original data not reviewed
Flag	:	Critical study for SIDS endpoint

08.01.2004 (12)

2.5 PARTITION COEFFICIENT

Partition coefficient	:	octanol-water
Log pow	:	= -.34 at °C
pH value	:	
Method	:	other (calculated): EPA
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Reliability	:	(2) valid with restrictions calculated value, no experimental data
Flag	:	Critical study for SIDS endpoint

09.09.2002 (9)

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in	:	other: miscible with water, ethanol, ethyl acetate, benzene, and chloroform; soluble in ether, n -butanol and carbon tetrachloride
Value	:	at °C
pH value	:	
concentration	:	at °C
Temperature effects	:	
Examine different pol.	:	
pKa	:	at 25 °C
Description	:	
Stable	:	
Remark	:	Estimated at 357,400 mg/l water by WSKOW v1.40
Reliability	:	(2) valid with restrictions original data not reviewed
Flag	:	Critical study for SIDS endpoint

06.09.2002 (18)

2.6.2 SURFACE TENSION

2.7 FLASH POINT

Value	:	= 143 °C
Type	:	open cup
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Reliability	:	(2) valid with restrictions original data not reviewed

06.09.2002 (28)

2.8 AUTO FLAMMABILITY

2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

2.11 OXIDIZING PROPERTIES

2.12 DISSOCIATION CONSTANT

2.13 VISCOSITY

Test type	:	other
Test procedure	:	
Value	:	= 2 - mPa s (dynamic) at 40 °C
Result	:	2.0 cP @40*C
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	
Remark	:	none
Reliability	:	(2) valid with restrictions original data not reviewed

08.01.2004 (29)

2.14 ADDITIONAL REMARKS

3.1.1 PHOTODEGRADATION

Type	:	air
Light source	:	
Light spectrum	:	nm
Relative intensity	:	based on intensity of sunlight
INDIRECT PHOTOLYSIS		
Sensitizer	:	OH
Conc. of sensitizer	:	
Rate constant	:	cm^3/(molecule*sec)
Degradation	:	= 50 % after 160 hour(s)
Deg. product	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	
Reliability	:	(2) valid with restrictions original data not reviewed
Flag	:	Critical study for SIDS endpoint

29.10.2002 (25)

3.1.2 STABILITY IN WATER

Deg. product	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	
Remark	:	Stable in water at 100deg. C; degrades rapidly at 125 deg. C in presence of alkalies.
Reliability	:	(2) valid with restrictions original data not reviewed
Flag	:	Critical study for SIDS endpoint

30.10.2002 (26)

3.1.3 STABILITY IN SOIL

3.2.1 MONITORING DATA

3.2.2 FIELD STUDIES

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type	:	fugacity model level III
Media	:	water - soil
Air	:	.0366 % (Fugacity Model Level I)
Water	:	45.2 % (Fugacity Model Level I)
Soil	:	54.7 % (Fugacity Model Level I)
Biota	:	% (Fugacity Model Level II/III)

Soil	:	% (Fugacity Model Level II/III)
Method	:	
Year	:	2002
Reliability	:	(2) valid with restrictions modeled value; no experimental data

29.10.2002 (30)

3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

Type	:	aerobic
Inoculum	:	activated sludge, domestic
Concentration	:	48.9 mg/l related to Test substance related to
Contact time	:	28 day(s)
Degradation	:	72.2 - 80.8 (±) % after 9 day(s)
Result	:	readily biodegradable
Deg. product	:	yes
Method	:	OECD Guide-line 301 B "Ready Biodegradability: Modified Sturm Test (CO2 evolution)"
Year	:	2003
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4

Method :

Deionized, purified, filtered water was used for this study. The microbial inoculum was activated sludge from the Columbia Wastewater Treatment Plant, Columbia, MO, which treats predominately domestic sewage. The sludge was prepared by filtering through glass wool; each reaction flask contained 1 mg/l of suspended solids. The activated sludge contained 2.6 x 10^6 colony forming units/ml of microorganisms, or 2.6 x 10^4 CFU/ml in the reaction flasks. To remove CO2, the incoming air was passed through an Ascarite column, followed by a trap of 5N KOH.

2.4 L of the test medium was placed in each of five 5L flasks, with 30 ml of activated sludge, and aerated and stirred for 24 hours prior to addition of test or reference compound. Reaction flasks were chosen at random for control 1, control 2, ethylene carbonate 1, ethylene carbonate 2, or sodium benzoate, reference compound. Ethylene carbonate was added to create a solution of 20 mg/l carbon, by addition of 146.7 and 146.8 mg ethylene carbonate, repectively, to the two replicates. Sodium benzoate solution was added to the reference flask to generate a solution of 20 mg/l carbon. Additional water was added to each of the flasks to give a total volume of 3 l.

The flasks were incubated in the dark at 22 C and stirred for 29 days with continual aeration by 50-100 ml/min CO2-free air. Off-gases were passed through three 100 ml 0.2N KOH traps; analysis for CO2 was performed on Days 2, 5, 7, 9, 14, 19, 23, 28, and 29. After day 28, an aliquote was removed from each reaction flask and analyzed for total carbon and inorganic carbon. Dissolved organic carbon (DOC) was calculated as the difference between total carbon and inorganic carbon.

Result : In the control solution, DOC was 0.35 mg C/l at study initiation and 0.15 mg C/l at termination. These values were subtracted from the DOC values for

the test flasks. For ethylene carbonate, the DOC was 20.2 and 20.6 mg C/l in the two replicates at initiation, and 1.75 and 2.30 mg C/l at termination. Thus, 91% and 89%, respectively, of the original DOC from ethylene carbonate was removed during the biodegradation study. This agrees with the evolution of CO2, which reported a total of 87% and 98.5% of the theoretical CO2 collected in the traps after 29 days. After 9 days of incubation, 72.2 and 80.8% of the theoretical CO2 had been collected.

Conclusion : Ethylene carbonate is readily biodegradable
Reliability : (1) valid without restriction
This study was conducted in a reliable laboratory according to the current test guideline and GLPs.
Flag : Critical study for SIDS endpoint
09.02.2004 (1)

Type : aerobic
Inoculum : domestic sewage, non-adapted
Concentration : 700 mg/l related to Test substance
related to
Contact time : 5 day(s)
Degradation : 100 (±) % after 5 day(s)
Result :
Kinetic of testsubst. : 3 hour(s) 4 %
2 day(s) 57 %
5 day(s) 100 %
%
%
Deg. product : not measured
Method : Directive 88/302/EEC, C.9
Year : 1995
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Method : Zahn-Wellens test based on loss of dissolved organic carbon.
Remark : The report presents only limited details of the study conduct and results.
Result : All dissolved organic carbon was removed by 5 days.
Conclusion : Readily biodegradable
Reliability : (2) valid with restrictions
Study conducted according to guideline in reliable laboratory, but report contains few details. No indication if study inspected by QAU.
09.02.2004 (8)

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

BCF : ca. 3.2
Elimination :
Method : other
Year :
GLP : no data
Test substance :

Reliability : (2) valid with restrictions
original data not reviewed
Flag : Critical study for SIDS endpoint
29.10.2002 (24)

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type	:	static
Species	:	Pimephales promelas (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
LC50	:	= 49000 measured/nominal
Limit test	:	
Analytical monitoring	:	no data
Method	:	other: ASTM-1980
Year	:	1983
GLP	:	no
Test substance	:	other TS
Method	:	static test; measured dissolved oxygen, pH, and temperature
Result	:	EC50 was 53,000 for fry; 49,000 for juvenile fish, and 57,000mg/l for subadult fish.
Test substance	:	Ethylene glycol
Reliability	:	(2) valid with restrictions Guideline study conducted on primary metabolite

08.01.2004 (23)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type	:	static
Species	:	Ceriodaphnia sp. (Crustacea)
Exposure period	:	48 hour(s)
Unit	:	mg/l
EC0	:	= 250 measured/nominal
EC50	:	= 5900 calculated
Analytical monitoring	:	no data
Method	:	EPA OPPTS 850.1010
Year	:	1992
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Conclusion	:	EC50 = 5900 mg/l
Reliability	:	(1) valid without restriction guideline study
Flag	:	Critical study for SIDS endpoint

08.01.2004 (20)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species	:	Microcystis aeruginosa (Algae, blue, cyanobacteria)
Endpoint	:	growth rate
Exposure period	:	7 day(s)
Unit	:	mg/l
LOEC	:	= 2000 calculated
Method	:	other: Cell multiplication inhibition test
Year	:	1975
GLP	:	no
Test substance	:	other TS
Method	:	Algal densities were determined by photoelectric measurement. Toxicity threshold is the value at which an inhibition of cell multiplication is seen

(equivalent to LOEC).

Test substance : Ethylene glycol
Reliability : (2) valid with restrictions
Guideline study on major metabolite
Flag : Critical study for SIDS endpoint
30.10.2002 (5)

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

In Vitro/in vivo	:	In vivo
Type	:	Metabolism
Species	:	rat
Number of animals		
Males	:	4
Females	:	
Doses		
Males	:	200 mg/kg
Females	:	
Vehicle	:	water
Route of administration	:	gavage
Exposure time	:	72 hour(s)
Product type guidance	:	
Decision on results on acute tox. tests	:	
Adverse effects on prolonged exposure	:	
Half-lives	:	1st: 0.25 hours 2nd: 3rd:
Toxic behaviour	:	
Deg. product	:	yes
Method	:	other
Year	:	1989
GLP	:	no data
Test substance	:	
Remark	:	degraded to ethylene glycol. 57% of administered dose (200 mg/kg) eliminated as CO2; 27% in urine within 72 hours. Ethylene carbonate disappearance from blood had a half-life of 0.25 hours.
Reliability	:	(1) valid without restriction adequate description, thorough study published in peer reviewed journal
Flag	:	Critical study for SIDS endpoint

30.10.2002 (11)

5.1.1 ACUTE ORAL TOXICITY

Type	:	LD50
Value	:	> 5000 mg/kg bw
Species	:	rat
Strain	:	Sprague-Dawley
Sex	:	male/female
Number of animals	:	10
Vehicle	:	
Doses	:	5000 mg/kg
Method	:	EPA OPP 81-1
Year	:	1990
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Conclusion	:	LD50> 5000 mg/kg
Reliability	:	(1) valid without restriction guideline study
Flag	:	Critical study for SIDS endpoint

30.10.2002 (21)

5.1.2 ACUTE INHALATION TOXICITY

5.1.3 ACUTE DERMAL TOXICITY

Type	:	LD50
Value	:	> 2000 mg/kg bw
Species	:	rat
Strain	:	Wistar
Sex	:	male/female
Number of animals	:	10
Vehicle	:	
Doses	:	dosed once at 2000 mg/kg
Method	:	OECD Guide-line 402 "Acute dermal Toxicity"
Year	:	1996
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	There were no deaths and no clinical signs of systemic reactions to treatment. There were no local dermal irritations. Four of 5 female rats had a slight body weight loss on day one, but after 14 days there were no treatment-related body weight effects. No treatment-related effects were seen at necropsy.
Reliability	:	(1) valid without restriction Guideline study performed in reliable laboratory according to GLP; full report reviewed.
Flag	:	Critical study for SIDS endpoint

09.02.2004 (16)

Type	:	LD0
Value	:	> 200 mg/kg bw
Species	:	rabbit
Strain	:	New Zealand white
Sex	:	female
Number of animals	:	3
Vehicle	:	water
Doses	:	dosed once at 200 mg/kg bw
Method	:	other: skin irritation study
Year	:	2001
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	500 mg test material applied to skin of 3 rabbits (body weight ~2.5 kg, range 2.48 to 2.82) for 4 hrs and covered with an occlusive dressing.
Conclusion	:	LD0 >200 mg/kg
Reliability	:	(2) valid with restrictions data from related test used
Flag	:	Critical study for SIDS endpoint

09.02.2004 (13)

5.1.4 ACUTE TOXICITY, OTHER ROUTES

5.2.1 SKIN IRRITATION

Species	:	rabbit
Concentration	:	
Exposure	:	Occlusive

Exposure time	:	4 hour(s)
Number of animals	:	3
Vehicle	:	water
PDII	:	.1
Result	:	slightly irritating
Classification	:	not irritating
Method	:	OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year	:	2001
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	62.5% in water, as a paste.
Reliability	:	(1) valid without restriction guideline study

29.10.2002 (14)

Species	:	rabbit
Concentration	:	100 %
Exposure	:	Semiocclusive
Exposure time	:	4 hour(s)
Number of animals	:	3
Vehicle	:	
PDII	:	0
Result	:	not irritating
Classification	:	not irritating
Method	:	OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year	:	2001
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4

30.10.2002 (3)

5.2.2 EYE IRRITATION

Species	:	rabbit
Concentration	:	undiluted
Dose	:	.1 ml
Exposure time	:	
Comment	:	not rinsed
Number of animals	:	3
Vehicle	:	none
Result	:	moderately irritating
Classification	:	not irritating
Method	:	OECD Guide-line 405 "Acute Eye Irritation/Corrosion"
Year	:	2001
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Reliability	:	(1) valid without restriction guideline study

29.10.2002 (15)

Species	:	rabbit
Concentration	:	undiluted
Dose	:	.1 ml
Exposure time	:	
Comment	:	not rinsed
Number of animals	:	3
Vehicle	:	none
Result	:	moderately irritating

Classification	:	not irritating
Method	:	OECD Guide-line 405 "Acute Eye Irritation/Corrosion"
Year	:	2001
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4

29.10.2002 (2)

5.3 SENSITIZATION

5.4 REPEATED DOSE TOXICITY

Type	:	Chronic
Species	:	rat
Sex	:	male/female
Strain	:	other: Crl: CD(SD)
Route of admin.	:	oral feed
Exposure period	:	78 weeks
Frequency of treatm.	:	continuous
Post exposure period	:	26 weeks
Doses	:	0, 25,000 and 50,000 ppm; males changed to 40,000 ppm at 44 weeks
Control group	:	yes, concurrent vehicle
NOAEL	:	< 25000 ppm
NOAEL Females	:	> 50000 ppm
Method	:	other
Year	:	1979
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4

Method : Diets mixed twice weekly and verified by analytical methods, fed to 26 males and 26 females of each group. Males fed 50,000 ppm for 42 weeks, allowed 2 weeks off and then at 40,000 ppm for 16 weeks. No hematology or clinical chemistry measurements were taken, but histopathology included: cerebrum, cerebellum, pituitary gland, spinal cord, vertebrae, lung, heart, mediastinum, thymus, thyroid gland, parathyroid gland, liver, spleen, pancreas, adrenal gland, kidney, urinary bladder, ovary, uterus or testis, accessory sex organ, esophagus, stomach, intestinal tract and gross lesions.

Remark : Crystals were thought by the authors to be oxalic acid, but no analytic confirmation was performed. Toxicity the same as with ethylene glycol, to which ethylene carbonate is rapidly converted.

Result : Reduced survival and body weights were found in both treated groups of males, but not females. All high dose males died by week 60; 10 low dose males survived to week 78. In females survival was 23 and 20 of 26 for low and high dose groups at 78 weeks.

Males, but not females, had severe nephrotoxicity including birefringent crystals in the convoluted tubules, collecting tubules, and sometimes, the renal pelvis and urinary bladder. Low dose males were not appreciably affected until after week 60.

There was no increase in tumors.

Reliability : (2) valid with restrictions
Limited description of organ effects, daily doses of chemical not reported.

Flag : Critical study for SIDS endpoint

08.01.2004 (31)

Type : Chronic

Species	:	rat
Sex	:	male/female
Strain	:	Fischer 344
Route of admin.	:	oral feed
Exposure period	:	24 months
Frequency of treatm.	:	daily
Post exposure period	:	none
Doses	:	0, 40, 200 and 1000 mg/kg/day
Control group	:	yes, concurrent vehicle
NOAEL	:	= 200 mg/kg
LOAEL	:	= 1000 mg/kg
Method	:	
Year	:	1976
GLP	:	no
Test substance	:	other TS
Method	:	130 males and females at each dose received ethylene glycol in the diet. Concentrations in the diet were adjusted after each body weight measurement to maintain a constant mg/kg/day intake. Interim sacrifices were conducted at 6 (10), 12 (10) and 18 months (20/sex/group). Clinical signs, body weights, food consumtion, hematology, clinical chemistry, and urinalysis periodically. Histopathology included: pituitary, brain, thyroid, parathyroids, adrenals, heart, spleen, mesenteric lymph nodes, trachea, lungs, ovaries, oviduct, submandibular salivary gland, esophagus , stomach, duodenum, jejunum, ileum, colon, liver, pancreas, spinal cord, uterus, testes, epididymides, prostate, kidneys, urinary bladder, eyes, skin, skeletal muscle, femur, sternum.
Result	:	Kidney pathology seen in high dose males (1000 mg/kg/day), along with increased water consumption, increased urine volume, increased kidney weight, increased mortality, changes in hematology, clinical chemistry and urinalysis, increased urinary oxalate crystals, and decreased urine specific gravity. In females, there was decreased urine volume and increased oxalate crystals and urine specific gravity; fewer hematology changes, and no clinical chemistry changes, were seen than in males. No adverse effects were seen in males or females at 200 mg/kg/day.
Test substance	:	ethylene glycol >99.93% pure
Reliability	:	(2) valid with restrictions Data on chief metabolite; half-life of ethylene carbonate is 0.25 hrs.

30.10.2002 (7)

5.5 GENETIC TOXICITY 'IN VITRO'

Type	:	Ames test
System of testing	:	Salmonella typhimurium strains TA98, TA100, TA1535, TA1537, TA1538
Test concentration	:	100, 333, 1000, 3333, 10000 ug/plate
Cycotoxic concentr.	:	none
Metabolic activation	:	with and without
Result	:	negative
Method	:	EPA OPPTS 870.5265
Year	:	1983
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Reliability	:	(1) valid without restriction guideline study
Flag	:	Critical study for SIDS endpoint

08.01.2004 (10)

Type	:	Unscheduled DNA synthesis
System of testing	:	rat primary hepatocytes

Test concentration	:	1 mg/ml to 10^-5 mg/ml
Cycotoxic concentr.	:	>1 mg/ml
Metabolic activation	:	
Result	:	negative
Method	:	EPA OTS 798.5550
Year	:	1984
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4

08.01.2004 (4)

17.06.2002

Type	:	other: Cell transformation
System of testing	:	BALB/3T3 cells
Test concentration	:	0.29 to 16250 ug/ml
Cycotoxic concentr.	:	8000 ug/ml
Metabolic activation	:	
Result	:	negative
Method	:	
Year	:	1983
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4

17.06.2002 (27)

5.6 GENETIC TOXICITY 'IN VIVO'

Type	:	Dominant lethal assay
Species	:	rat
Sex	:	male
Strain	:	Fischer 344
Route of admin.	:	oral feed
Exposure period	:	134 days
Doses	:	0, 40, 200, and 1000 mg/kg/day
Result	:	negative
Method	:	Directive 88/302/EEC, B.22
Year	:	1977
GLP	:	no
Test substance	:	other TS
Method	:	F2 male pups from a multigeneration study received ethylene glycol in the diet from weaning (day 21) to 155 days of age. At 155 days, males were mated with untreated females for 3 weekly periods.
Result	:	There were no treatment-related effects on percentage of pregnant rats, total number of early fetal deaths per pregnant female, or median number of fetal deaths in any of the three mating periods.
Test substance	:	Ethylene glycol; the primary metabolite of ethylene carbonate
Reliability	:	(2) valid with restrictions Standard test on primary metabolite; half life for metabolism of ethylene carbonate is 0.25 hr.
Flag	:	Critical study for SIDS endpoint

08.01.2004 (6)

5.7 CARCINOGENICITY

5.8.1 TOXICITY TO FERTILITY

Type	:	other: continuous breeding
Species	:	mouse
Sex	:	male/female
Strain	:	CD-1
Route of admin.	:	drinking water
Exposure period	:	7 day premating; 98-day cohabitation period; 21-day segregation period
Frequency of treatm.	:	continuous
Premating exposure period		
Male	:	7 days
Female	:	7 days
Duration of test	:	126 days
No. of generation studies	:	1
Doses	:	0, 0.25, 0.5 and 1.0% = 0, 410, 840 and 1640 mg/kg/day
Control group	:	yes, concurrent vehicle
NOAEL parental	:	> 1640 mg/kg bw
NOAEL F1 offspring	:	= 840 mg/kg bw
Result	:	slight reduction in pup weight, number of litters/fertile pair and number of live pups per litter at 1640 mg/kg/day. Unusual facial features (short snout, wide-set eyes) and skeletal defects were seen in F1 offspring at 1640 mg/kg/day.
Method	:	other: NTP Continuous Breeding Assay
Year	:	1985
GLP	:	no
Test substance	:	other TS
Test substance	:	ethylene glycol, principle metabolite of ethylene carbonate
Reliability	:	(2) valid with restrictions The study is considered reliable with restrictions because the test was performed on the metabolite, not the test material.

08.01.2004 (17)

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species	:	rat
Sex	:	female
Strain	:	Sprague-Dawley
Route of admin.	:	gavage
Exposure period	:	days 6-15 of gestation
Frequency of treatm.	:	once daily
Duration of test	:	observed to day 20 of gestation
Doses	:	0, 750, 1500, 3000 mg/kg/day
Control group	:	yes, concurrent vehicle
NOAEL maternal tox.	:	= 1500 mg/kg bw
NOAEL teratogen.	:	= 750 mg/kg bw
Method	:	other: EPA Guideline 1984
Year	:	1990
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Reduced weight gain at 3000 mg/kg/day gestation days 6-9 (13.8, 9.8*, 11.3, 1.5* grams gain for 0, 750, 1500, and 3000 mg/kg/day group); weight gain days 9-12, 12-15 and 15-20 comparable. Post-dose salivation seen in 13 of 24 dams at 3000 mg/kg/day; in one rat one day at 1500 mg/kg/day. There was no effect on the number of fetuses/litter, resorptions, or sex ratio. Mean fetal weight was reduced at 1500 and 3000 mg/kg/day (3.8, 3.7, 3.5*, and 3.2*, respectively). At 3000 mg/kg/day, there was an

increase in the number of fetuses and the number of litters with malformations. Soft tissue malformations (including hydrocephalus, umbilical herniation, gastroschisis, cleft palate and misshapen and compressed stomach) occurred in 1, 0, 0, and 21 pups in 1,0, 0, and 10 litters, and skeletal malformations (including fused, bifurcated ribs, and missing ribs) occurred in 0, 1, 0, and 11 fetus in 0, 1, 0, and 6 litters. Ethylene carbonate is rapidly converted to ethylene glycol in mammlian organisms; therefore, developmental effects from ethylene carbonate would be expected to be similar to those seen from ethylene glycol. Administration of ethylene glycol to rats and mice by gavage gestation days 6-15 resulted in similar skeletal defects at 1500 mg/kg/day, with a NOEL of 500 mg/kg/day. (Neeper-Bradley et al. (1995). Determination of a no-observed effect level for developmental toxicity of ethylene glycol administered by gavage to CD rats and CD-1 mice. Fundam. Appl. Toxicol. 27:121-130.) Thus, developmental toxicity from ethylene carbonate is likely caused by its conversion to ethylene glycol.

Reliability : (1) valid without restriction
guideline study

Flag : Critical study for SIDS endpoint

08.01.2004 (22)

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

28.10.2002

5.9 SPECIFIC INVESTIGATIONS

5.10 EXPOSURE EXPERIENCE

5.11 ADDITIONAL REMARKS

6.1 ANALYTICAL METHODS

6.2 DETECTION AND IDENTIFICATION

7.1 FUNCTION

7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED

7.3 ORGANISMS TO BE PROTECTED

7.4 USER

7.5 RESISTANCE

8.1 METHODS HANDLING AND STORING

8.2 FIRE GUIDANCE

8.3 EMERGENCY MEASURES

8.4 POSSIB. OF RENDERING SUBST. HARMLESS

8.5 WASTE MANAGEMENT

8.6 SIDE-EFFECTS DETECTION

8.7 SUBSTANCE REGISTERED AS DANGEROUS FOR GROUND WATER

8.8 REACTIVITY TOWARDS CONTAINER MATERIAL

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10.1 END POINT SUMMARY

10.2 HAZARD SUMMARY

10.3 RISK ASSESSMENT